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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,622	06/04/2001	Kent Davey	2103.047	4056

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EXAMINER
DAY, HERNG DER

ART UNIT	PAPER NUMBER
2128	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/873,622	DAVEY, KENT	
	Examiner	**Art Unit**	
	Herng-der Day	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 May 2006.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to Applicant's Reply ("Reply") to Office Action dated January 24, 2006, mailed May 23, 2006, and received by PTO May 25, 2006.

1-1. Claims 1-9 and 11 are pending.

1-2. Claims 1-9 and 11 have been examined and rejected.

Specification

2. The disclosure is objected to because of the following informalities:

Appropriate correction is required.

2-1. It appears that the "V", as shown in the newly added equation (25), should be "∇".

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re

Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,527,695 B1 issued to Davey et al., in view of Ruohonen, "Transcranial Magnetic Stimulation: Modelling and New Techniques", Doctoral Thesis, Department of Engineering Physics and Mathematics, Helsinki University of Technology, 1998, pages 1-50 (IDS 10, filed February 7, 2005).

The conflicting claims are all directed to maximizing stimulation by using the same membrane voltage equation for optimizing parameters including core reluctance and winding resistance. In other words, in claim 1, although this instant application recites more detailed steps in computing core reluctance using a boundary element analysis for the core, wherein the core is assumed to have a one-turn inductance in step b) and in computing a value for the inner and outer core radii using specified analysis and algorithm in steps d) and e), these steps are not non-obvious over the limitations of "selecting an optimal reluctance" and "selecting an optimal

winding resistance" as recited in claim 2 of U.S. Patent No. 6,527,695 B1, because without optimizing calculation there are no values for selecting optimal values to maximize stimulation by using membrane voltage equation.

However, this instant application does have an additional limitation "a) allowing the inner and outer core radii to change parametrically in a nested loop". Nevertheless, Davey et al., in U.S. Patent No. 6,527,695 B1, do suggest, "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" (column 7, lines 41-45).

Ruohonen discloses modeling TMS and using the developed models as a basis for engineering modifications that would increase the utility of TMS (page 4, paragraph 3). Specifically, Ruohonen discloses "Coil design must always be taken into account when constructing TMS equipment" (page 23, paragraph 2), "In one study, a mathematical method was used to maximise the focality by changing the *coil shape*" (page 23, paragraph 1) and "Problems with power consumption and coil heating can be alleviated by reducing the coil's resistance, determined by the *wire gauge* and *coil geometry*" (page 23, paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Davey et al. to incorporate the teachings of Ruohonen because as suggested by Davey et al., "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" and also suggested by Ruohonen, "Coil design must always be taken into account when constructing TMS equipment", "a mathematical method was used to maximise the focality by changing the coil shape", and "Problems with power consumption and coil heating can be alleviated by reducing the coil's

resistance, determined by the wire gauge and coil geometry". In other words, from Ruohonen's suggestion of "changing the *coil shape*" and "determined by the *wire gauge* and *coil geometry*", therefore, "allowing the inner and outer core radii to change" would have been obvious to one of ordinary skill in the art. Furthermore, from Davey et al., "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" suggests a magnetic optimization problem, therefore, "core radii to change parametrically in a nested loop" would have been obvious to one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davey et al. ("Davey1"), U.S. Patent 6,527,695 B1 issued March 4, 2003, in view of Ruohonen, "Transcranial Magnetic Stimulation: Modelling and New Techniques", Doctoral Thesis, Department of Engineering Physics and Mathematics, Helsinki University of Technology, 1998, pages 1-50 (IDS 10, filed February 7, 2005) and further in view of Davey ("Davey2"), "Use of Tensor Product Splines in Magnet Optimization", IEEE Transactions on Magnetics, Volume 35, Issue 3, May 1999, pages 1714-1717.

6-1. Regarding claim 1, Davey1 discloses a computerized method of optimizing properties of a magnetic core, the core having inner and outer radii and windings (core and N turns windings,

FIG. 1 (a)), the computerized method having computer-executable instructions for performing the following:

b) computing core reluctance, number of turns, and winding resistance for each position (reluctance, winding resistance, column 2, lines 49-62; number of turns, column 8, lines 53-55), wherein the core reluctance is computed using a boundary element analysis for the core, wherein the core is assumed to have a one-turn inductance (boundary element, column 8, lines 63-65);

c) computing the maximum induced membrane voltage based on the following equation (equation (17), columns 5-6);

Davey1 fails to expressly disclose a) allowing the inner and outer core radii to change parametrically in a nested loop. Nevertheless, Davey1 does suggest, "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" (column 7, lines 41-45).

Ruohonen discloses modeling TMS and using the developed models as a basis for engineering modifications that would increase the utility of TMS (page 4, paragraph 3). Specifically, Ruohonen suggests "Coil design must always be taken into account when constructing TMS equipment" (page 23, paragraph 2), "In one study, a mathematical method was used to maximise the focality by changing the coil shape" (page 23, paragraph 1) and "Problems with power consumption and coil heating can be alleviated by reducing the coil's resistance, determined by the wire gauge and coil geometry" (page 23, paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Davey1 to incorporate the teachings of Ruohonen to obtain the invention as specified in steps a) to c) of claim 1 as suggested by Davey1 and Ruohonen. In

other words, from Ruohonen's suggestion of "changing the *coil shape*" and "determined by the *wire gauge* and *coil geometry*", therefore, "allowing the inner and outer core radii to change" would have been obvious to one of ordinary skill in the art. Furthermore, from Davey et al., "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" suggests a magnetic optimization problem, therefore, "core radii to change parametrically in a nested loop" would have been obvious to one of ordinary skill in the art.

Davey1 also fail to expressly disclose d) fitting the maximum induced membrane voltage to the inner and outer core radii using a multi-variable spline analysis and e) using a variable metric sequential quadratic program algorithm to compute a value for the inner and outer core radii that maximizes the maximum induced membrane voltage. Nevertheless, Davey1 does suggest, "selecting an optimal winding resistance", "the optimal frequency, optimal reluctance, optimal capacitance and/or the optimal winding resistance are selected to maximize stimulation of a peripheral nerve cell" (column 2, lines 49-62), and "The maximization of the nerve stimulation is achieved by maximizing the membrane voltage (Abstract).

Davey2 discloses the usefulness of tensor product splines in magnetic optimization (Abstract). It includes the following steps: "(1) analyze the problem over the range of positions sought, (2) perform a functional fit to the index to be minimized, (3) employ a directed optimization technique (e.g., variable metric) to obtain the optimal solution, (4) verify that the functional fit is valid by varying the starting guess using a Monte Carlo method, (5) verify the accuracy of the prediction and if necessary repeat 1-4 over a smaller range" (page 1714, left column, the last paragraph). Furthermore, "The technique requires first collection data; this is

performed using a parametric analysis in which the parameters are allowed to vary in a nested loop" (page 1717, right column, paragraph 3). An exemplary application has been demonstrated to select the inner and outer die shape that minimizes the departure of the field in the cavity from the target value specified (pages 1715-1716, section IV. Application; A. Team Workshop problem # 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combined teachings of Davey1 and Ruohonen to incorporate the teachings of Davey2 to obtain the invention as specified in claim 1 because of the identified usefulness of tensor product splines in magnetic optimization as suggested by Davey2 in the demonstrated application to select the inner and outer die shape.

6-2. Regarding claim 2, Davey2 further discloses comprising the step of:

f) repeating step e) with a Monte Carlo starting guess algorithm (varying the starting guess using a Monte Carlo method, page 1714, left column, the last paragraph), wherein said step f) insures that a global maximum is found (Multiple Monte Carlo restarts can rapidly check the internal space to avoid local wells, page 1714, right column, the first paragraph).

6-3. Regarding claim 3, Davey1 further discloses said method is performed with a preselected wire size (The resistance of 20 mΩ approximates that of 6.09 m (20') of #10 gauge wire with no skin effect, column 10, lines 34-36).

6-4. Regarding claim 4, Davey1 further discloses comprising the initial step of selecting a wire size (The resistance of 20 mΩ approximates that of 6.09 m (20') of #10 gauge wire with no skin effect, column 10, lines 29-36).

6-5. Regarding claim 5, Davey1 further discloses comprising the initial step of selecting a wire size (The resistance of 20 mΩ approximates that of 6.09 m (20') of #10 gauge wire with no skin effect, column 10, lines 29-36).

6-6. Regarding claim 6, Davey1 further discloses comprising the steps of:

g) selecting different wire sizes (the resistance of 45 mΩ approximates the same wire treated as solid copper tube with skin effect near 8 kHz, column 10, lines 36-38), and

h) repeating steps a-e for each different wire size selected (The increase in resistance results in a 9.2% decrease in membrane stimulation voltage for the same energy, column 10, lines 38-39).

6-7. Regarding claim 7, Davey1 further discloses comprising the steps of:

g) selecting different wire sizes (the resistance of 45 mΩ approximates the same wire treated as solid copper tube with skin effect near 8 kHz, column 10, lines 36-38), and

h) repeating steps a-f for each different wire size selected (The increase in resistance results in a 9.2% decrease in membrane stimulation voltage for the same energy, column 10, lines 38-39).

6-8. Regarding claim 8, Davey1 further discloses comprising the step of:

i) selecting the wire size which maximizes the membrane voltage (keeping the exciting circuit resistance small, column 10, line 65, through column 11, line 1).

6-9. Regarding claim 9, Davey1 further discloses comprising the step of:

i) selecting the wire size which maximizes the membrane voltage (keeping the exciting circuit resistance small, column 10, line 65, through column 11, line 1).

6-10. Regarding claim 11, Davey1 further discloses comprising manufacturing a magnetic core (constructing said magnetic nerve stimulator, column 13, lines 8-9).

Applicant's Arguments

7. Applicant argues the following:

7-1. Objections to the Specification

(1) "Applicant has amended the specification to include relevant portions of the material that was incorporated by reference in the as-filed application at p. 11, in connection with steps e and f." (Page 7, paragraph 2, Reply).

7-2. Claim Rejection - 35 U.S.C. §112, First Paragraph

(2) "Applicant respectfully submits that the amendments to the specification discussed above also overcome the Examiner's rejection of claims 1-9 and 11 under 35 U.S.C. §112, first paragraph." (Page 7, paragraph 3, Reply).

7-3. Double Patenting Rejection

(3) "both Davey 1 and Ruohonen fail to teach or suggest the claimed 'allowing the inner and outer core radii to change parametrically in a nested loop.' Thus, even if the teachings of Davey 1 and Ruohonen were combined, they would not teach or suggest the claimed invention to a skilled artisan." (Page 9, paragraph 3, Reply).

7-4. Claim Rejection - 35 U.S.C. §103(a)

(4) "Applicant respectfully submits that Davey 1 and/or Ruohonen, either taken alone or in combination, fail to teach or suggest the subject matter of claims 1-9 for the reasons discussed

above in connection with the present Reply's discussion of the obviousness-type double patenting rejection." (Page 9, paragraph 4, through page 10, paragraph 1, Reply).

Response to Arguments

8. Applicant's arguments have been fully considered.

8-1. Applicant's argument (1) is persuasive. The objections to the specification in Office Action dated January 24, 2006, have been withdrawn.

8-2. Applicant's argument (2) is persuasive. The rejections of claims 1-9 and 11 under 35 U.S.C. 112, first paragraph, in Office Action dated January 24, 2006, have been withdrawn.

8-3. Applicant's arguments (3)-(4) are not persuasive. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).

Davey et al., in U.S. Patent No. 6,527,695 B1, suggest, "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" (column 7, lines 41-45). On the other hand, Ruohonen suggest, "Coil design must always be taken into account when constructing TMS equipment" (page 23, paragraph 2), "In one study, a mathematical method was used to maximise the focality by changing the coil shape" (page 23, paragraph 1) and "Problems with power consumption and coil heating can be alleviated by reducing the coil's resistance, determined by the wire gauge and coil geometry" (page 23, paragraph 5). Based on the suggestions of both Davey et al. and Ruohonen, it would

have been obvious to one of ordinary skill in the art at the time the invention was made to combine both teachings to maximize the membrane voltage by reducing the winding resistance through determining optimal wire gauge and coil geometry including inner and outer core radii. In other words, from Ruohonen's suggestion of "changing the *coil shape*" and "determined by the *wire gauge* and *coil geometry*", therefore, "allowing the inner and outer core radii to change" would have been obvious to one of ordinary skill in the art. Furthermore, from Davey et al., "The choice of the inner radius depends on a optimized balance between decreasing the reluctance and decreasing the resistance" suggests a magnetic optimization problem, therefore, "core radii to change parametrically in a nested loop" would have been obvious to one of ordinary skill in the art.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Herng-der Day
July 7, 2006 H.D.

ThaiPhan
Thai Phan
Patent Examiner
AU: 2128